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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,899	08/31/2001	Arnold Miller	AM-4A	3897

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EXAMINER
BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No. 09/944,899	Applicant(s) MILLER, ARNOLD	
	Examiner Jessica R Baxter	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 August 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites the limitation "first end of said delivery tube" in page 53 line 5. There is insufficient antecedent basis for this limitation in the claim. The delivery tube has third and fourth ends.

5. Claim 21 recites the limitation "first end of said delivery tube" in Page 61 line 5. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 15 recites the limitation "Dacron/PTFE". It is unclear what is meant by this limitation. Is the material meant to contain both Dacron and PTFE or one or the other.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-6, 8-11, 13-15, 21, 22 and 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,416,522 to Strecker in view of U.S. Patent No. 5,957,940 to Tanner et al.

Regarding claims 1 and 21, Strecker discloses an apparatus comprising a surgical fastener (securing means 4), a delivery tube (hollow body 89) having third and fourth ends, first and second tube portions adjacent to said third and fourth ends (FIG. 12), and forming a longitudinal axis between the third and fourth ends, said delivery tube including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a stressed condition to an unstressed condition (FIG. 12 and Column 10 lines 25-41), said third stressed elongate shape enabling said third end to be extended through an endovascular pathway (FIG. 14), said fourth unstressed shape being formed with said first and second tube portions being configured at an angle to one another (FIG. 12 and 15); delivery tube deployment

means being configurable between a first position and a second position, said first position of said delivery tube deployment means restraining said delivery tube in said third stressed elongate shape, and said second position of said delivery tube deployment means releasing said delivery tube in the fourth unstressed shape (Column 10 lines 11-24); penetration means adjacent said third end of said delivery tube (Column 6 lines 22-28 and Column 10 lines 48-54), said penetration means being configured to pierce through a vascular structure in the endovascular pathway; and insertion means adjacent to said first end of said delivery tube (FIG. 12 pusher 98), said insertion means being configured to place said surgical fastener through the vascular structure pierced by said penetration means. Strecker discloses the claimed invention except for the fastener being in the form of a spring with a plurality of coils around a spring axis, with said coils being spring biased towards each other along said spring axis with sufficient axial force so as to enable coils on opposite sides of layers to clamp the layers of material together along the spring axis. Tanner teaches a coil spring fastener that is linear when stored in the delivery device and maintains a coiled configuration after delivery. Tanner also teaches that this fastener applies compressive forces to opposite sides of the materials that are being fastened together so that the two layers are securely fastened together (Column 22 line 63- Column 24 line 36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the coil spring fastener of Tanner with the delivery device of Strecker in order to securely fasten the graft to the vessel wall.

Regarding claim 2, Strecker further discloses a plurality of delivery tubes being controlled by said delivery deployment means (FIG. 12 catheter 90 and receiving sections 93).

Regarding claim 3, Strecker discloses the material has superelastic properties (Column 10 lines 25-41).

Regarding claim 4, Strecker discloses that the material is Nitinol (see Column 4 lines 50-57).

Regarding claims 5 and 25, Strecker discloses that the penetration means is a sharpened cutting edgeformed on the third end of the delivery tube (Column 6 lines 22-28).

Regarding claims 6 and 26, Strecker discloses that the penetration means is a sharpened cutting edge formed on the first end of the surgical fastener (Column 10 lines 48-54).

Regarding claims 8 and 27, Strecker discloses that said insertion means is a plunger being configured within said delivery tube, said plunger having first and second portions, said first and second portions being configured adjacent said third and fourth ends of said delivery tube, respectively, said first end of said plunger being configured adjacent said second end of said fastener, whereby movement of said plunger a predetermined distance toward the third end of said delivery tube forces said fastener through said vascular structure a distance corresponding to said predetermined distance (Column 10 lines 42-65).

Regarding claims 9 and 10, Strecker discloses a guide wire and a balloon catheter supported by the guide wire (Column 12 line 62-Column 13 line 4).

Regarding claim 11, Strecker discloses that the balloon catheter provides a reference for the placement of said fasteners (FIG.16 and 19 and Column 12 line 62 – Column 13 line 4).

Regarding claim 13, Strecker discloses an endovascular graft being in surrounding configuration to said third of said delivery tube wherein said fastener fastens the graft to the vascular structure in the endovascular pathway (FIG. 12 graft 87 and securing means 4).

Regarding claim 14, Strecker further discloses balloon inflation (Column 8 line 65 – Column 9 line 26).

Regarding claim 15, Strecker discloses the claimed invention except for the use of DACROn/PTFE to construct the endovascular graft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the materials of DACRON/PTFE,

since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claim 19, Strecker discloses an outer endovascular delivery sheath being in slidable, surrounding configuration (see FIG. 12 catheter 90).

Regarding claim 20, placing the device in an aorta does not add any structural limitations to the claim. Strecker's device may be placed in an aorta. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.

Regarding claim 22, Strecker discloses that the step of placing said delivery tube adjacent said vascular structure includes using a guide wire to position said delivery tube (Column 12 line 62 – Column 13 line 4).

Regarding claim 28, Strecker discloses further comprising the step of withdrawing said delivery tube away from the plurality of portions of material to release said surgical fastener from said stressed condition on said second end of said surgical fastener whereby said surgical fastener clamps the plurality of layers of the material together (Column 12 lines 40-61).

Regarding claim 29, Strecker discloses that one of said plurality of portions of material comprises a vascular structure (vessel 1), and further wherein another of said plurality of portions of material comprises a graft (graft 87).

Regarding claim 31, Strecker discloses that said graft is placed in said vascular structure prior to positioning said apparatus for inserting a surgical fastener in said vascular structure (see Column 10 lines 11-24).

9. Claims 16, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker '522 in view of Tanner et al. '940 as applied to claims 1-6, 8-11, 13-15, 21, 22 and 25-31 above, and

further in view of U.S. Patent No. 5,843,164 to Frantzen et al. Strecker discloses the claimed invention except for the use of a stent surrounding the graft. Frantzen discloses a stent for attaching the graft to the vessel wall. The stent that is provided has an open weave structure that provides high flexibility and promotes tissue growth. The expansion of the stent encourages the fixation of the graft to the vessel wall (Column 3 lines 5-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the stent of Frantzen with the graft implantation system of Strecker, as modified, in order to encourage the fixation of the graft to the vessel wall and to encourage tissue growth into the stent graft combination.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to fastener delivery devices and grafts:

U.S. Patent No. 5,078,726 to Kreamer

U.S. Patent No. 5,782,844 to Yoon et al.

U.S. Patent No. 6,113,611 to Allen et al.

U.S. Patent No. 6,287,317 to Makower et al.

U.S. Patent No. 6,346,111 to Gordon et al.

U.S. Patent No. 6,358,258 to Arcia et al.

U.S. Patent No. 6,379,366 to Fleischman et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization

where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

jrb
December 16, 2002

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700